DEC STD 005-0 OPERATIONAL ALERT (OPAL) PROCEDURE

DOCUMENT IDENTIFIER: A-DS-EL00005-00-0 Rev E1, 19-May-1989

ABSTRACT: This document describes how an Operational Alert (OPAL) message is authorized and issued to alert the corporation to a product that has a safety defect or a serious functional defect.

APPLICABILITY: Mandatory for all Digital hardware products.

STATUS:APPROVED 19-May-1989; see EL-INDEX-00 for expiration date.

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1 INTRODUCTION

1.1 OPAL OVERVIEW

An Operational Alert (OPAL) message is a formal notification issued to key company organizations, alerting them to a product defect and providing a strategy for minimizing the impact of the product defect. If possible, the OPAL message should provide a solution to the problem; otherwise, the solution should follow as soon as possible.

The OPAL message applies to two types of product defects, a safety defect or a serious functional defect. Both types of defects are covered by this standard.

A product safety defect OPAL message is issued for any defect in design or manufacture, whether Digital-produced or supplier-produced, in a product, unit, or system. The message is issued after investigation by Field Service Product Safety (FSPS) and judged by the Quick Action Committee (QAC) as a potential safety hazard.

A serious functional defect OPAL message is issued for a defect occurring repeatedly, throughout a significant quantity of production, that could render a product, unit, or system unfit for its intended use. These defects include, but are not limited to, critical malfunction, nonfunction, or premature failure.

A serious functional defect should be assessed according to the specific situation in which it occurs. The impact the defect has, or might have, on the entire corporation should be the primary consideration. For example, an OPAL message would not be issued if all affected hardware units are still in the volume plant, or enroute to systems plants that can be quickly notified by other means. A serious functional defect OPAL message must contain, or be followed by, specific actions to correct the problem and to prevent recurrence.

Other communication methods such as Product Hold, Engineering Hold, Manufacturing Hold, and Component Alert should be used at the specific plant, region, or area level where the problem exists to disseminate information about a safety defect or a serious functional defect that does not involve the entire corporation. These communication methods prevent unnecessary alarm and concern by groups not affected by the specifics of the communication, and they allow a restricted audience to more efficiently address the problem (refer to Section 2.5).

1.2 SCOPE

This standard establishes the procedures and responsibilities for issuing and following up on any OPAL message. It also establishes procedures and responsibilities for responding to any OPAL message.

This standard identifies the managers authorized to initiate an OPAL message, see subheads 2.1 and 2.2, and states the information content required in any OPAL message, heading 4.

DEC STD 005-1 In-Plant Product Hold Procedure defines the procedure that might be initiated by an OPAL message.

1.3 RESPONSIBILITIES

Any employee of Digital is responsible for reporting a defect in product safety or product function.

1.3.1 Manufacturing Group Quality Managers

Manufacturing Group Quality Managers issuing a serious functional defect OPAL message shall do so in accordance with the requirements of this standard, and are responsible for the technical content of this section. The Manufacturing Group Quality Manager is also responsible for redistribution of a product safety OPAL to his plants, verifying receipt, and ensuring that required actions have been taken.

For additional information, contact Henry Singer, Manufacturing Product Safety and Regulations Manager, WJO1-1/D7, DTN: 282-1660, PLANET::HSINGER.

1.3.2 Plant Managers and Quality Managers

Plant Managers and Quality Managers are responsible for the implementation of this procedure whenever an OPAL requires action within their plant. When the plant receives an OPAL, the Plant/Quality Manager will send a confirmation of receipt. In addition, when involved in originating an OPAL, they are responsible for the technical content and follow-through to the OPAL closure.

1.3.3 Corporate Product Safety and Regulations Manager

The Corporate Product Safety (CPS & R) Manager chairs the Quick Action Committee, see subhead 1.3.9, and issue an immediate OPAL message if the product safety defect clearly constitutes an unacceptable risk of personal injury or property damage. The Manufacturing Product Safety and Reguations manager is responsible for issuing numbers from the OPAL log after the message has been cleared by the Law Department.

1.3.4 Engineering Managers

Engineering Managers are responsible for providing input to correct a product safety or serious functional defect after being notified of a possible OPAL message being issued.

1.3.5 Product Managers/Business Managers

Product Managers and Business Managers are responsible for providing input to correct a product safety or serious functional defect after being notified of a possible OPAL message.

1.3.6 Law Department

The member of the Law Department responsible for the affected product shall review the text of an OPAL message before it is issued to ensure appropriate wording. Call DTN: 223-2132, and ask to contact the responsible lawyer for the specific product/area.

1.3.7 Manufacturing Product Safety and Regulations

The MPSR Manager, Henry Singer (DTN: 282-1660), is responsible for sending the OPAL message via ENET to designated individuals, when instructed to do so by one of the following:

a. Quick Action Committee

b. Corporate Product Safety Manager

c. Manufacturing Group Quality Manager

1.3.8 Field Service Product Safety

The Field Service Product Safety group will investigate the product safety incident and determine whether an imminent or substantial safety hazard exists.

1.3.9 Quick Action Committee (QAC)

When the Corporate Product Safety and Regulations Manager receives notification of a potential OPAL from Field Service Product Safety, the Corporate Product Safety and Regulations Manager or authorized representative, convenes the QAC to assess the need to issue a product safety OPAL message (refer to *DEC STD 424-0 Digital Product Safety Handbooks*.

2 REQUIREMENTS

2.1 PRODUCT SAFETY DEFECTS

The person who perceives a product safety defect shall immediately notify the local product safety representative. If the local product safety representative is not available, notify Field Service Product Safety at DTN: 276-9242, (617) 496-9242, or at the following alternate numbers:

DTN: 276-9238, (617) 496-9238
DTN: 276-9236, (617) 496-9236

During nonworking hours, the Field Service Product Safety 24-hour emergency number is (617) 646-0220.

For Europe, contact the 24-hour Product Safety Emergency Incident Reporting Hotline in Valbonne, France [33] 93.65 53 53.

For the United Kingdom, during working hours, contact [44] [256] 57122.

The Corporate Product Safety and Regulations Manager, or authorized representative, may issue an OPAL message for a product with a safety defect. Corporate Product Safety shall issue an immediate OPAL message if the product safety defect clearly constitutes an imminent or substantial hazard.

The Group Quality Manager of the affected location shall be notified. Refer to *DEC STD 005-1 In-Plant Product Hold Procedure* if it is necessary to implement a product hold.

A list of the Manufacturing Group Quality Managers that makes up QBOD Board of Directors and the Groups they represent follows.

Name	Group
Vic Aramati	Semiconductor Operations Group Quality Manager
Glenn Armbruster	CSM Group Quality Manager
Tony Basso	Terminals Group Quality Manager
Guido Ciannavei	Storage Systems Group Quality Manager
Guido Mardones	GIA Group Quality Manager
Paul McGaunn	Manufacturing Customer Satisfaction Manager (QBOD Chairperson)
Tony Mongillo	Small Systems Customer Satisfaction Manager

Name	Group
Hank Palumbo	U.S. Area Operations Group Quality Manager
TBD	External Resources Quality Manager
Carmine Tata	PWB Group Quality Manager
Derek Wood	European Group Quality Manager

2.2 SERIOUS FUNCTIONAL DEFECTS

The person who perceives a serious functional defect that is clearly not a safety hazard shall notify the responsible Quality Manager as soon as possible. If there is any reason to believe that the defect could be a product safety defect, follow the procedure in subhead 2.1.

The responsible Quality Manager shall notify the functional or area Group Quality Manager. The functional or area Group Quality Manager shall contact the Manufacturing Group Quality Manager of the last manufacturing location.

The Manufacturing Group Quality Manager, after collecting all pertinent information, shall notify the principal managers: Product Manager, Engineering Manager, Systems Manufacturing Manager, Customer Services Systems Engineering, Field Service, the Law Department person responsible for the affected product, and any other functional organizations affected.

Before generating the OPAL message, these individuals shall determine the seriousness of the functional defect and the risks involved, how many defective units have been shipped, and whether an OPAL message to all possible recipients is necessary. This determination ensures that a clear understanding exists regarding the impact of the OPAL message on the corporation.

a. When the principal managers recommend issuing an OPAL message, only the following individuals are authorized to do so.

   1. Manufacturing Group Manager

   2. Manufacturing Group Quality Manager

b. When the Manufacturing Group Manager or Manufacturing Group Quality Manager rejects the recommendation to issue an OPAL message, the decision must be clearly documented and copies submitted to the following:

   1. Original requestor

   2. Producing location(s)

   3. Principal managers

c. When the principal managers recommend against issuing an OPAL message, and the Manufacturing Group Manager or Manufacturing Group Quality Manager agrees, then an alternate method to resolve the issue should be proposed, properly documented, and sent to the following:

   1. Original requestor

   2. Producing location(s)

   3. Principal managers

d. When the principal managers recommend against issuing an OPAL message, but the Manufacturing Group Manager or Manufacturing Group Quality Manager disagrees with the recommendation, the Manufacturing Group Manager or Manufacturing Group Quality Manager may issue an OPAL message.

2.3 NOTIFICATION

A Manufacturing Group Quality Manager or Manufacturing Group Manager, when originating an OPAL message, shall contact the Manufacturing Product Safety Manager to obtain the next OPAL number in the log.

The OPAL message is then reviewed by the Law Department. A Manufacturing Group Quality Manager, Manufacturing Group Manager, or the Corporate Product Safety Regulations Manager, or authorized representative, shall then contact the Manufacturing Product Safety and Regulations Manager to issue the OPAL message. Notification of other individuals affected by the OPAL message is the responsiblity of the managers listed on the General First-issue Distribution List. For further details regarding this list, see heading 5 of this document.

2.4 ACKNOWLEDGEMENT

Recipients of an OPAL message must acknowledge receiving the message by ENET to the originator within 24 hours, see subhead 5.1. Each recipient is responsible for having a documented internal response system for OPAL messages. Acknowledgement must consist of the return of the entire OPAL message to Manufacturing Product Safety and Regulations Manager.

2.5 NON-OPAL PROCEDURES FOR OTHER DEFECTS

The OPAL system is to be used only to communicate actions to be taken on product safety or serious functional defect that affect the whole corporation. It is not to be misused to communicate technical tips, product operating instructions, or problems that can be quickly contained and resolved within a specific area.

The following procedures are available for reporting and requesting corrective action on product defects:

a. *DEC STD 005-2 Hardware Products Non-compliant With Digital Standards.*

b. A-SP-7665069-0-0 *Corrective Action Request Procedure.*

The OPAL message does not replace an Engineering Change Order (ECO) or a Field Change Order (FCO). However, an ECO or FCO may often follow an OPAL message.

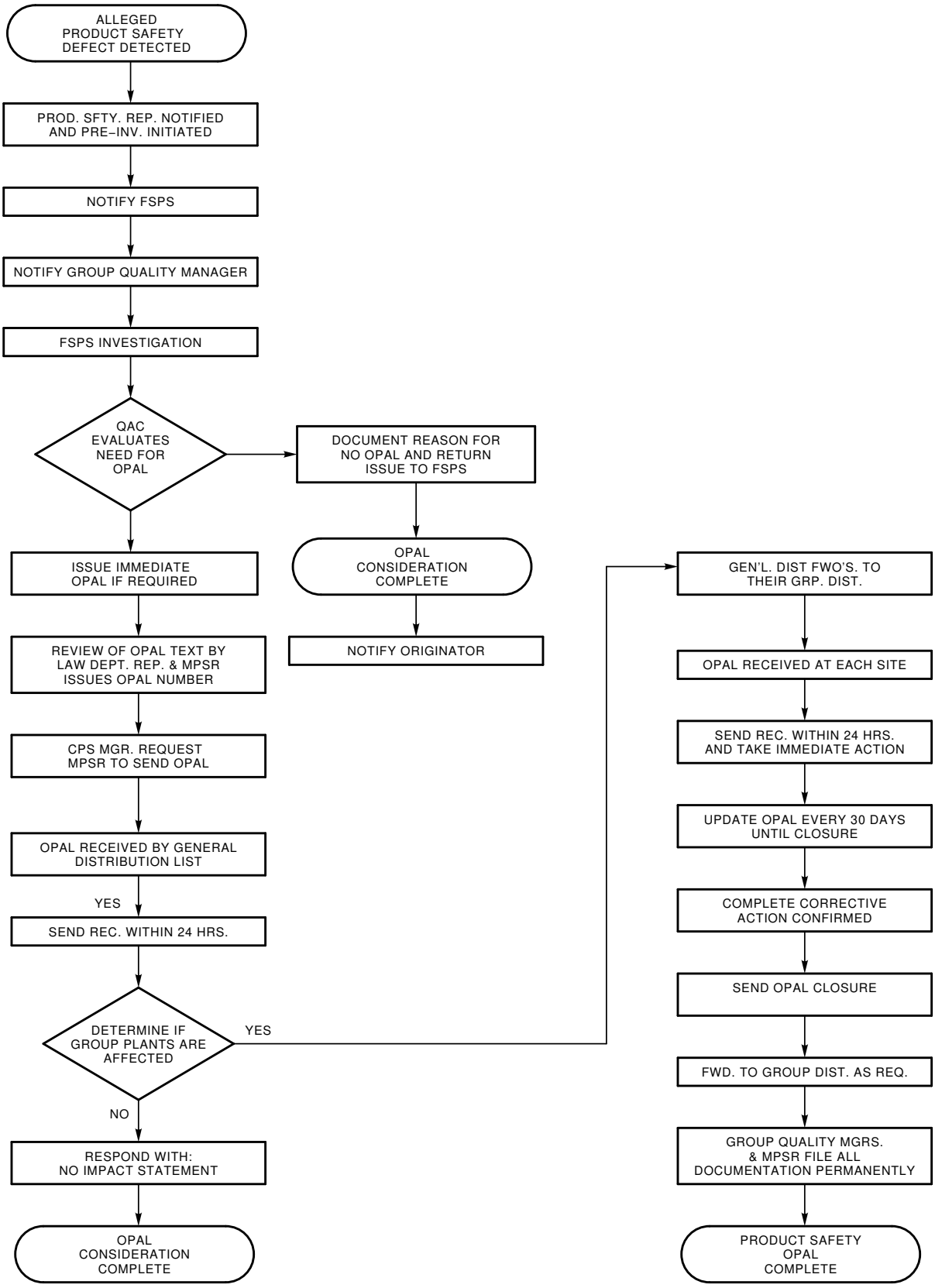
3 IMPLEMENTATION

3.1 PRODUCT SAFETY DEFECT OPAL PROCEDURES

Refer to Figure 1, Product Safety Defect OPAL Procedures Flow Chart.

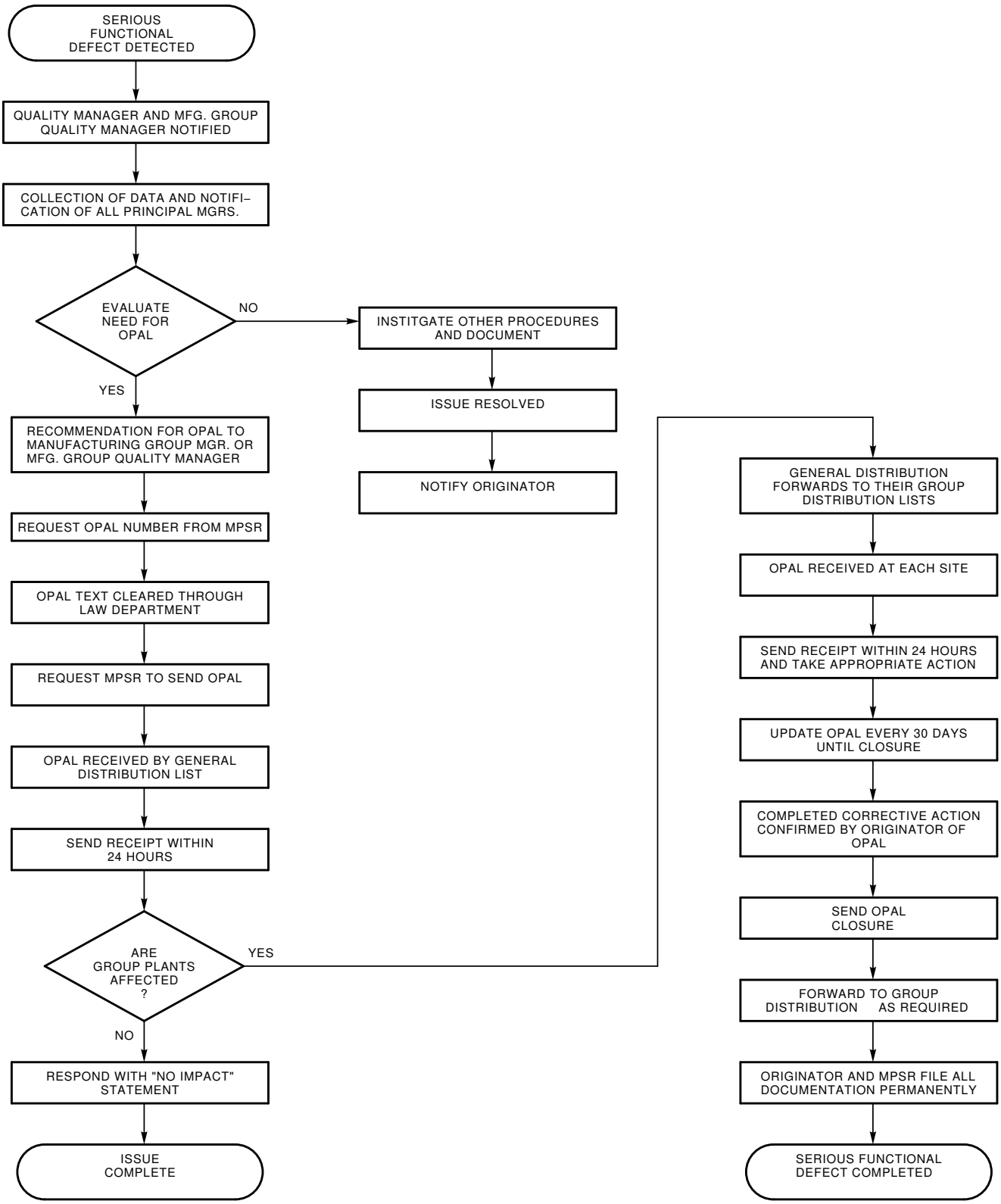
1. Alleged product safety defect detected.

Figure 1: Product Safety Defect OPAL Procedures Flow Chart


ALLEGED PRODUCT SAFETY DEFECT DETECTED
PROD. SFTY. REP. NOTIFIED AND PRE–INV. INITIATED
NOTIFY FSPS
NOTIFY GROUP QUALITY MANAGER
FSPS INVESTIGATION
QAC EVALUATES NEED FOR OPAL
DOCUMENT REASON FOR NO OPAL AND RETURN ISSUE TO FSPS
OPAL CONSIDERATION COMPLETE
NOTIFY ORIGINATOR
ISSUE IMMEDIATE OPAL IF REQUIRED
REVIEW OF OPAL TEXT BY LAW DEPT. REP. & MPSR ISSUES OPAL NUMBER
CPS MGR. REQUEST MPSR TO SEND OPAL
OPAL RECEIVED BY GENERAL DISTRIBUTION LIST
YES
SEND REC. WITHIN 24 HRS.
DETERMINE IF GROUP PLANTS ARE AFFECTED
YES
NO
RESPOND WITH: NO IMPACT STATEMENT
OPAL CONSIDERATION COMPLETE
GEN'L. DIST FWO'S. TO THEIR GRP. DIST.
OPAL RECEIVED AT EACH SITE
SEND REC. WITHIN 24 HRS. AND TAKE IMMEDIATE ACTION
UPDATE OPAL EVERY 30 DAYS UNTIL CLOSURE
COMPLETE CORRECTIVE ACTION CONFIRMED
SEND OPAL CLOSURE
FWD. TO GROUP DIST. AS REQ.
GROUP QUALITY MGRS. & MPSR FILE ALL DOCUMENTATION PERMANENTLY
PRODUCT SAFETY OPAL COMPLETE

2. The local product safety representative is notified and initiates pre-investigation procedures contained in *DEC STD 005-5 - Manufacturing Product Safety Policy and Procedure for Pre-Investigation of Alleged Product Safety Incidents.*
3. The local product safety representative notifies Field Service Product Safety.
4. The group Quality Manager is notified.
5. Field Service Product Safety investigation per *DEC STD 132-3 Digital Field Service Product Safety Policies and Procedures Manual - Investigation of Alleged Product Safety Incidents and Problem Resolution of Product Safety Hazards.*
6. Corporate Product Safety and Regulations Manager or authorized representative convenes the Quick Action Committee to determine the need to issue a product safety OPAL message.
7. If an OPAL is not necessary, document the reason and return the issue to Field Service Product Safety and notify originator.
8. If an immediate OPAL is required, the Corporate Product Safety and Regulations Manager or authorized representative issues a product safety OPAL message after text approval by the Law Department representative. MPSR issues the OPAL number.
9. Manufacturing Product Safety Manager or authorized representative transmits the OPAL message via ENET to General First-issue Distribution List.
10. Recipients of a first-issue OPAL message must acknowledge receipt within 24 hours to the Manufacturing Product Safety Manager or designee specified in the OPAL message and indicate if their group is affected. See header 2.4.
11. Recipients of a first-issue OPAL message retransmit the message via ENET to their group distribution lists, if applicable.
12. If the group is not affected, send a "no impact statement" to the originator.
13. Recipients of an OPAL message must acknowledge receipt within 24 hours to Manufacturing Product Safety and Regulations and notify the appropriate Group Quality Manager or designee specified in the OPAL that acknowledgement has been sent to MPSR. See header 2.4.
14. The originator of an OPAL message must issue OPAL updates at least every 30 days to report status. Repeat steps 9 through 13 for each update.
15. Completed corrective action is confirmed to Corporate Product Safety, Field Service Product Safety, Manufacturing Product Safety and Regulations and the affected Group Quality Manager.
16. OPAL Closure Notice (issued by the originator) is transmitted by Manufacturing Product Safety Manager to General First-issue Distribution List.
17. Recipients of OPAL Closure Notice retransmit notice to their group distribution lists, if applicable.
18. Group Quality Managers maintain a copy of the OPAL Closure Notice in their permanent OPAL file.
19. Manufacturing Product Safety maintains the originals of all OPAL correspondence in a permanent file. Recipients of all OPAL correspondence must also maintain a permanent file.

Figure 2: Serious Functional Defect PAL Procedures Flow Chart


SERIOUS FUNCTIONAL DEFECT DETECTED
QUALITY MANAGER AND MFG. GROUP QUALITY MANAGER NOTIFIED
COLLECTION OF DATA AND NOTIFI– CATION OF ALL PRINCIPAL MGRS.
EVALUATE NEED FOR OPAL
NO
INSTITGATE OTHER PROCEDURES AND DOCUMENT
ISSUE RESOLVED
NOTIFY ORIGINATOR
YES
RECOMMENDATION FOR OPAL TO MANUFACTURING GROUP MGR. OR MFG. GROUP QUALITY MANAGER
REQUEST OPAL NUMBER FROM MPSR
OPAL TEXT CLEARED THROUGH LAW DEPARTMENT
REQUEST MPSR TO SEND OPAL
OPAL RECEIVED BY GENERAL DISTRIBUTION LIST
SEND RECEIPT WITHIN 24 HOURS
ARE GROUP PLANTS AFFECTED ?
YES
NO
RESPOND WITH "NO IMPACT" STATEMENT
ISSUE COMPLETE
GENERAL DISTRIBUTION FORWARDS TO THEIR GROUP DISTRIBUTION LISTS
OPAL RECEIVED AT EACH SITE
SEND RECEIPT WITHIN 24 HOURS AND TAKE APPROPRIATE ACTION
UPDATE OPAL EVERY 30 DAYS UNTIL CLOSURE
COMPLETED CORRECTIVE ACTION CONFIRMED BY ORIGINATOR OF OPAL
SEND OPAL CLOSURE
FORWARD TO GROUP DISTRIBUTION AS REQUIRED
ORIGINATOR AND MPSR FILE ALL DOCUMENTATION PERMANENTLY
SERIOUS FUNCTIONAL DEFECT COMPLETED

3.2 SERIOUS FUNCTIONAL DEFECT OPAL PROCEDURES

Refer to Figure 2, Serious Functional Defect OPAL Procedures Flow Chart.

1. Serious functional defect detected.
2. Quality Manager notified.
3. Manufacturing Group Quality Manager notified.
4. Manufacturing Group Quality Manager, or representative, collects pertinent information and notifies principal managers: Product Manager, Design Engineering Manager, Systems Manufacturing Manager, Customer Services Systems Engineering, Field Service, and Law Department.
5. Principal managers analyze and evaluate the need for an OPAL message.
6. If the principal managers recommend that an OPAL message be issued, the recommendation is made to the Manufacturing Group Manager or the Manufacturing Group Quality Manager, the only individuals authorized to issue the message.
7. If the Manufacturing Group Manager or Manufacturing Group Quality Manager disagrees with the recommendation, they may elect to institute other procedures. This must be properly documented and notify the originator.
8. If the Manufacturing Group Manager or Manufacturing Group Quality Manager agrees with the recommendation to issue an OPAL message, an OPAL log number is obtained from Manufacturing Product Safety and Regulations, DTN: 282-1660.
9. The text of an OPAL message is cleared through the Law Department.
10. Manufacturing Group Quality Manager or Manufacturing Group Manager requests Manufacturing Product Safety and Regulations to transmit the OPAL message to General First-Issue Distribution List.
11. Recipients of original OPAL message retransmit the message via ENET to their group distribution lists, if applicable.
12. Recipients of OPAL message acknowledge receipt of the message within 24 hours. See header 2.4.
13. Originating Manufacturing Group Quality Manager or Manufacturing Group Manager issues OPAL updates at least every 30 days to report status. Repeat steps 10 through 12 for each update.
14. Completed corrective action is confirmed to originating Manufacturing Group Quality Manager or Manufacturing Group Manager.
15. An OPAL Closure Notice is sent by the originating Manufacturing Group Quality Manager or Manufacturing Group Manager by OPAL message. Repeat steps 10 through 12.
16. Recipients of an OPAL Closure Notice retransmit the notice to their group distribution lists.
17. Originating Manufacturing Group Quality Manager maintains a copy of the OPAL Closure Notice in a permanent OPAL file.
18. Manufacturing Product Safety maintains all OPAL correspondence in a permanent file. Recipients of all OPAL correspondence must also maintain a permanent file.

4 OPAL INFORMATION CONTENT REQUIREMENTS

The originator of an OPAL is responsible to ensure that the following information is required for all OPAL messages. The original message should include as much information as possible; OPAL updates can communicate required information not included in the original message.

a. OPAL Category. Indicate either product safety defect or serious functional defect.

b. Name of Product. Name the option, assembly, or part affected to include the following:

1. Option designation, assembly number, and part number.
2. Part revision designator(s).
3. What the part or assembly is used on, that is, next higher assembly.
4. Manufacturer or Digital internal source(s).
5. Serial numbers, lot numbers, and date codes affected.

c. Defect Description. Be concise and complete and include how the defect affects the function or safety of the product.

d. Affected Locations. List all facilities that have or may have received the product.

e. Action Plan. Specify the actions to be taken at the affected Manufacturing and Field Service facilities, including the fix procedure if it is known and practical at the time the OPAL message is originated. If the fix procedure is not available, it should follow as soon as possible and include the following information:

1. Persons responsible for the actions.
2. Required schedule to complete.
3. Rework procedures, test procedures, material procurement, and marking to identify the corrected component/product affected.
4. Any actions already taken.
5. What will constitute closure of the OPAL message.

f. Charge number for the activities required by the OPAL.

g. Originator's Name. Include ENET note, DTN, location, and mail stop.

4.1 RECORD RETENTION

Copies of the following documents concerning each OPAL message must be forwarded to Henry Singer, Manufacturing Product Safety and Regulations Manager, at WJO/D7 or PLANET::HSINGER within five working days from the time the message was originated.

a. Incident report

b. Incident investigation report

c. OPAL text

d. OPAL replies

e. OPAL activities

f. OPAL closure

g. Documentation of telephone communications that is relevant to the OPAL message

It is imperative that a complete file of each OPAL message be maintained permanently at a central location, because of the legal liabilities that the corporation can be subjected to.

4.2 RELEASE OF INFORMATION

All oral or written communications regarding an OPAL message shall be considered and handled as Company Confidential. Information that pertains to a product safety hold shall not be released or distributed outside of Digital unless authorized by Corporate Product Safety, Field Service Product Safety, Manufacturing Product Safety and Regulations, the Law Department and Risk Management.

5 OPAL DISTRIBUTION LISTS

To update an OPAL Distribution List, forward the following information to Henry Singer, WJO1-1/D7, DTN: 282-1660.

a. Name

b. Type of update (add, delete, change)

c. Location/Mailstop

d. ENET node

e. Badge number

f. Group, plant, or organization represented

g. Name of list to be updated

5.1 GENERAL FIRST-ISSUE DISTRIBUTION LIST

This list is intended to ensure that everyone with operation responsibility is notified. Individuals on the General First-Issue Distribution List must acknowledge the OPAL message within 24 hours. See header 2.4.

5.2 THE GROUP DISTRIBUTION LIST

This list is maintained by the recipients on the General First-Issue List, and they should use it when retransmitting the OPAL message to their groups. Individuals on this list must acknowledge the OPAL message within 24 hours. See header 2.4.

APPENDIX A

REFERENCED DOCUMENTS

EL-Class Digital Documents

EL-Class Number	Document Title
EL-00005-01	*DEC STD 005-1 In-Plant Product Hold Procedure*
EL-00005-02	*DEC STD 005-2 Hardware Products Non-Compliant with Digital Standards*
EL-00005-05	*DEC STD 005-5 Manufacturing Product Safety Policy and Procedure for Pre-investigation of Alleged Product Safety Incidents*
EL-00132-03	*DEC STD 132-3 Digital Field Service Product Safety Policies and Procedures Manual - Investigation of Alleged Product Safety Incidents and Problem Resolution of Product Safety Hazards*
EL-00424-00	*DEC STD Digital Product Safety Handbook*
76-65069-00	*DEC STD Corrective Action Request Procedure*

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